Attorney Docket No.: 99.25US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Cioca, et al.

Serial No.: 09/838,649 Group Art Unit: 1617

Filed: April 19, 2001 Examiner: Wells, Lauren Q.

For: Stable Antimicrobials in Structured Water

RESPONSE PURSUANT TO 37 CFR 1.116 - Remarks

The pending claims, Claims 1 to 5, 9 to 12, 20, and 22 are rejected under 35 U.S.C. §112, second paragraph because, according to the Examiner, the phrase "characterized by" is vague and indefinite. In particular, the Examiner questions, whether the water always has a conductivity and pH values as recited in the claim or is it associated with such a conductivity and pH value. The word "characterized" is one that is quite familiar to one of ordinary skill in the art as many compounds must be characterized according to certain chemical and physical properties. An interpretation of the term "characterized" with "association" as suggested by the Examiner is not what one that would be made by one of ordinary skill in the art. The standard for §112 is not based on the Examiner's interpretation but rather on that of the ordinarily skilled artisan.

To support the interpretation that would held by one of ordinary skill in the art Applicants submit herewith several documents demonstrating the use of the term "characterize" by the skilled artisan in the same manner as Applicants use the term in the present claims. First, the dictionary entries for "characterize" begin to establish the essence of the word and it is quite contrary to the term "association" suggested by the Examiner. Indeed, opposite to an association, the term "characterize" means to distinguish and describe distinctive qualities and/or traits of a material. Second, a summary of an exemplary textbook in chemistry entitled "Reactions and Characterization of Solids" is provided. This summary introduces the concept that materials, such as in the present case of structured water, are characterized. This summary goes on to note that general physical properties are discussed. This is noteworthy because it is through the determination of physical properties that materials are characterized. Finally, an International Union of Pure and Applied Chemistry (aka IUPAC) project information from the Inorganic Chemistry Division of the Physical and Biophysical Chemistry Division is provided. The title is "Standardization of methods for the characterization of inorganic membranes." The first objective is to indicate the physical and physico-chemical techniques for the characterization. Second, the object is to determine the properties. This is similar to the structured water in the present invention.

The physical properties of structured water that are of particular importance in the present invention are pH and conductivity values. Thus, these values are provided to distinguish the structured water and the term "characterized" as it is used in the present claims is fully understood by one of ordinary skill in the art. Further, the reference cited by the Examiner, namely U.S. Patent No. 6,139,855, uses the term "characterized" in a very similar manner to the present invention. The standards and rules of patentability are to be applied in a uniform manner. MPEP 706. Therefore, Applicants believe that the use of "characterized" in the present claims is fully understood by one of ordinary skill in the art and respectfully request that this rejection be withdrawn.

The pending claims of the present invention are again rejected for being obvious in view of Cioca et al. (U.S. Patent No. 6,139,855; hereinafter "the '855 reference") and Beerse et al. (U.S. Patent No. 6,217,887). According to the Examiner Claim 22 directed to a method of preserving a composition by adding **structured water of Claim 1** is evidence that structured water of the '855 can also be added to a composition to preserve. Applicants respectfully traverse because the structured water of Claim 1 in the present invention, as amended, is not the structured water of the '855 reference. The structured water of the '855 reference is not made from the same feed water of the present invention and consequently, does not contain within its cluster structures, the active in the '855 compositions. Nor is this taught or suggested in the '855 reference. The structured water of Claim 1 as it was previously explained in Applicants' Response of June 4, 2003 is distinguishable from the structured water of the '855 reference. A review of the '855 reference is pertinent in that it reveals the distinct differences between it and the present invention. Specifically, in Claim 1 the '855 invention is described as follows.

> 1. A . . . composition containing a structured water component comprising a combination of I and S water, wherein I water is characterized by a conductivity of about 500-3000 μS and pH of about 2.0-3.0; S water is characterized by a conductivity of about 600-2500 μS, and a pH of about 10-12, each resulting from starting water with μS/cm of about 250-450, and a pH of about 7-7.5.

The '855 reference fails to teach or suggest incorporating the active in the cluster structure of the I and S water. Rather, there is only mention of the active added to I and S water. Therefore, the '855 reference fails to teach or suggest the present invention where the anti-microbial is incorporated in the structured water. See also, Example II, at column 5, lines 36 to 37, "[c]affeine is added at a level to a series of different vehicles. In the present invention, the antimicrobial is added feed water to make structured water. The antimicrobial is added to deionized water with particular cluster structure stabilizing ionic component. This is likewise not disclosed by the '855 reference. In the present specification, the feed water for cluster stabilization in the present invention is provided at page 7, lines 16 to 25. The feed water for cluster stabilization in the present invention has a pH of about 6.0 to 6.4 and a C (μS/cm) of about 470 to

520. This is in contrast with the '855 starting water which is taught in Claim 1 of the '855 reference as having a pH of about 7 to 7.5 and 250 to 450 μS/cm.

The structured water of the present invention, as amended, is distinguishable from the '855 structured water in two ways. First, as a result of making structured water from a combination of feed water and the antimicrobial agents, the antimicrobial agents are incorporated in the cluster structures of the structured water. And second, the feed water of the present invention is different than the '855 starting water. Thus, the '855 reference fails to teach or suggest structured water having the antimicrobial incorporated within its cluster structures as it is in the present invention.

The cited prior art reference, namely the '855 reference, fails to teach or suggest the identical subject matter of the present invention because it fails to teach or suggest the incorporation of its actives within the cluster structure of the structured water and because it fails to teach or suggest the feed water of the present invention. The combination of structured water and active agents in a composition is different than the incorporation of antimicrobial agents within the cluster structure of structured water, and therefore, a *prima facie* case of obviousness has not been made. In rejecting claims under 35 U.S.C. §103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Rijckaert*, 28 USPQ2d 1955, 1956 (CAFC 1993) (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.* "A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *Id.*, (citing *In re Bell* , 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (quoting *In re Rinehart*, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)). Since a *prima facie* case of obviousness has not been made, for reasons which are discussed above, the burden of coming forward with evidence or data regarding inherent properties has not shifted to Applicants.

The Examiner finds also that Applicants' arguments are mere statements and not evidence. Previously, Applicant argued as they do herein that "two antimicrobial agents are incorporated within the cluster structure of structured water. As a result, the silver ions do not precipitate out of the structured water of the present invention. This serves as evidence of the difference between the present invention and the mere addition of silver salts [sic] to structured water." Applicants assert that this is not a mere statement but rather is supported by the present specification at page 12, lines 18 to 20. "When the silver ions and potassium sorbate are present within the cluster structure of structured water, the antimicrobial structured water is stable and does not succumb to the threat of instability. . . " Further, at page 2, lines 3 to 7, the instability of silver ions is discussed. In particular, it is noted that after time, stability efforts fail and "silver particles still settle out. . . . Other alternatives to colloidal silver [ ] have been proposed to avoid the stability problems associated with the monovalent silver ions. . . . " Thus, Applicants' argument regarding the lack

of precipitation of silver ions out of the cluster structures of structured water are statements fully supported by the present specification.

The other combination of references is Cioca et al. and Stroud et al., however, the same situation arises when making this combination as does with the previous combination of cited references. Therefore, because the combination of Cioca et al. and Stroud et al. fails to remedy the defect of Cioca et al, the primary reference, Applicants assert that this combination of references also fails to render the present invention obvious. In the '855 reference, the only teaching or suggestion with respect to the combination of structured water and biological actives is as separate entities. Further, there is no teaching or suggestion in the '855 reference of the feed water having the pH of about 6.0 to 6.4 and a conductivity of about 470 to 520, and treating both the antimicrobial and the specific feed water of the present invention to integrate the antimicrobial in the cluster structure of the structured water. Therefore, the '855 reference in combination with any other reference that fails to remedy this defect will not render the present invention obvious and a *prima facie* case of obviousness has not been made. As the claims of the present application are believed to be in condition for allowance, issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

Date: October 15, 2003

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3 entries found for *characterize.*

char·ac·ter·ize Pronunciation Key (kăr'ək-tə-rīz')
tr.v. **character·ized, character·iz·ing, character·iz·es**

1. To describe the qualities or peculiarities of: *characterized the warden as ruthless.*
2. To be a distinctive trait or mark of; distinguish: *the rash and high fever that characterize this disease; a region that is characterized by its dikes and canals.*

char'ac·ter·iz'er *n.*

characterize

\Char"ac*ter*ize\, v. t. [imp. & p. p. Characterized; p. pr. & vb. n. Characterizing.] [LL. characterizare, Gr. ?: cf. F. charact['e]riser.] 1. To make distinct and recognizable by peculiar marks or traits; to make with

distinctive features.

European, Asiatic, Chinese, African, and Grecian faces are Characterized. --Arbuthnot.

2. To engrave or imprint. [Obs.] --Sir M. Hale.

3. To indicate the character of; to describe.

Under the name of Tamerlane he intended to characterize King William. --Johnson.

4. To be a characteristic of; to make, or express the character of.

The softness and effeminacy which characterize the men of rank in most countries. --W. Irving.

Syn: To describe; distinguish; mark; designate; style; particularize; entitle.

Source: *Webster's Revised Unabridged Dictionary, © 1996, 1998 MICRA, Inc.*

characterize

v 1: describe the qualities or peculiarities of; "You can characterize his behavior as that of an egotist"; "This poem can be characterized as a lament for a dead lover" [syn: qualify] 2: be characteristic of; "What characterizes a Venetian painting?"

Source: *WordNet ® 1.6, © 1997 Princeton University*

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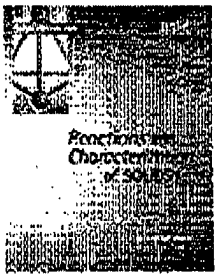

ISBN 0 85404 612 7

Reactions and Characterization of Solids

by Sandra E Dann

The last twenty years or so has seen a change in the perception of solid state chemistry, in particular scientific significance of understanding the relationship between chemical structure and physical properties. As such, it now forms an important part of both mainstream chemistry and material science degrees.

Reactions and Characterization of Solids is designed as an introductory text with plenty of illustrative examples to reinforce the essentials of the topic. In the first few chapters, the fundamental principles of elementary crystal chemistry are introduced, together with the principles of both preparing and characterising materials in the solid state. Some elementary thermodynamics are also included at this stage to introduce the idea of bond strength as a method of determining and predicting compound stability.

General physical properties such as electronic and magnetic behaviour are discussed, together with specific topics relating to solid state materials such as non-stoichiometry. Furthermore, several solid state materials are described in detail, relating the fundamental properties and structural behaviour covered throughout the book, to real systems and working materials.

Publication Date May 2000
Hard/Softback Softback
Extent vi + 202 pages

* Preface
* Contents
* Sample

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Physical and Biophysical Chemistry Division (I)
and
Inorganic Chemistry Division (II)

Number: 2000-002-2-100

Title: Standardization of methods for the characterization of inorganic membranes

Task Group
Chair: Ed Yi Hua Ma

Members: L. Cot, J.A. Dalmon, Imre Dekany, Douglas Fain, John Falconer, J.H. Fendler, Hubert Fleming, George R. Gavalas, W.S. Winston, Eiichi Kikuchi, William J. Koros, Y.S. Lin, Vladimir Linkov, Shin-ichi Nakao, Richard D. Noble, John Pellegrino, J.D.R. Ramsay, Jesus Santamaria, Theodore T. Tsotsis, J. Douglas Way, Nanping Xu - *to be completed by addition of members from both industry and academics*

Remarks: part of the Strategic Initiative on Materials

Completion Date: 2003

Objective:

1. To indicate the practical capabilities of physical and physico-chemical techniques for, specifically, the characterization of inorganic membranes.
2. To recommend an efficient methodology for the determination of inorganic membrane properties of practical importance.
3. To draw attention to unresolved or unaddressed issues which deserve experimental attention.

Description:
In the past decade, there has been a rapid growth in the number of publications dealing with synthesis and characterization of in rganic membranes. Furthermore,

the increased industrial interest has been demonstrated by the recent formation of two multi-consortiums to develop inorganic membranes for partial oxidation of methane to synthesis gas. Such a large increase in the interest in the development of a new generation of inorganic membranes is, at least, due in part to their excellent chemical, thermal and mechanical stability. We can certainly expect a wide variety of applications of inorganic membranes, along with polymeric membranes, to be developed in the decades to come. Therefore, the development of standard characterization procedures for the evaluation and comparison of the important characteristics of inorganic membranes is essential to facilitate information exchange among researchers and industrial practitioners and to enhance the membrane development.

The project contents are:

1. Organization of a half-day workshop to address issues and techniques involved in the characterization of inorganic membranes. The format of the workshop will be 5-6 invited lectures given by experts in the field of inorganic membranes followed by a panel discussion. > see Progress section
2. Characterization of physical properties of inorganic membranes including, but not limited to, porosity, pore size distribution, membrane thickness and streaming potential. The emphasis will be on the well-established general techniques such as mercury porosimetry, adsorption and desorption isotherms, calorimetric determinations, SEM, TEM, NMR and AFM.
3. Transport property characterization by dynamic techniques including rejection measurements, liquid/gas methods (e.g., bubble point, liquid expulsion permporometry), liquid/liquid displacement porosimetry, liquid/gas permeance measurements and permporometry.
4. Development of standards for protocols, data analysis and reporting formats.
5. Development of standards for experimental conditions for characterization including temperature, pressure, standard gases and single and mixture gas measurements.

In addition to the organization of two workshops, the following additional steps will be taken to carry out the project.

1. Forming a Working Party consisting of leading experts from both academia and industry;
2. Providing a summary on currently published characterization techniques;
3. Conducting surveys among academic and industrial researchers to obtain additional information on characterization techniques and suggestions for new techniques;
4. Selecting a preliminary list of suggested standardized characterization methods by the Working Party;
5. Distributing the preliminary list to the people working in the field for comments and suggestions;
6. Formulating the final recommendations by the Working Party to IUPAC for review and approval.

Progress :

A half-day workshop was held in conjunction with the 6th International Conference on Inorganic Membranes in Montpellier, France, June 26-30, 2000.

This project was presented at a poster session at the IUPAC Congress/GA July 2001
>view pdf - 206KB<

Last update: 5 August 2001

If you want to update this information, contact us by e-mail
Do not forget to include the Project Number, your name and relation with that project